December 11, 2020

Mr. David Sorensen
Cardiac Pacemakers Inc. / Boston Scientific Corporation
4100 Hamline Ave N
Arden Hills, MN 55112

Dear Mr. Sorensen:

On November 30, 2020, TRC Environmental Corporation (TRC) performed a test to determine the Ethylene Oxide (EtO) removal efficiency of one 3M GSC8 Sterilizer/Abator system at the Arden Hills facility. This letter summarizes the results of that test.

The test consisted of the collection of simultaneous samples of the gas stream entering and leaving the EtO control system during the EtO removal cycle that lasted about 15 minutes. Evacuated summa cannisters were used to collect the EtO. The cannisters were analyzed for EtO via gas chromatography using modified EPA Method 18 and California Air Resources Board (CARB) method 431. The results of the test are presented in the following table:

Test Location	EtO Concentration (ppm)	EtO Control Device Removal Efficiency (%)
Abator Inlet (Upstream tap)	2,661	99.9812%
Abator Outlet (Downstream tap)	< 0.50 [BDL]	

* Outlet results were below the detection limit of the analysis method which was 0.5 ppm.

If you have any questions regarding this information, please let me know. We appreciate the continuing opportunities to provide you with our services.

Sincerely,

TRC Environmental Corporation

David Wainio
Senior Project Manager

Field Notes and Lab Results Summary
Boston Scientific - 3M GS8X Abator System Date: 11/30/2020

Upstream Tap Cannister:	000380	Start Pressure:	28 in. Hg	End Pressure: 24 in. Hg
Downstream Tap Cannister:	000093	Start Pressure:	27 in. Hg	End Pressure : 22 in. Hg

Ambient Pressure from Abator was 987 mb, Chamber temp was 55 deg C.
Notes: System EtO evacuation cycle was started at 1002 and cannisters were opened to begin sampling. Chamber pressure started at 503 mb and fell to around 165 mb in 15 min. Once evacuation cycle was complete, cannister valves were closed and sampling was complete at 1017. Outlet loading was below the lab detection limit of 0.5 ppm so 0.5 ppm was used for the efficiency calculation.

Effieciency Calculation

	PPM
Abator Upstream Tap (Inlet)	2661
Abator Downstream Tap (Outlet)	0.5
Total Loading	2661
Outlet Loading	<0.5
% Efficiency	99.98121

Atmospheric Analysis & Consulting, Inc.

CLIENT	:	TRC
PROJECT NAME	:	Boston Scientific 3M Abator EtO
PROJECT NUMBER	:	397311
AAC PROJECT NO.	:	202163
REPORT DATE	:	12/03/2020

On December 1st, 2020, Atmospheric Analysis & Consulting, Inc. received two (2) Six-Liter Summa Canisters for Ethylene Oxide analysis by EPA 18 Modified. Upon receipt, the samples were assigned unique Laboratory ID numbers as follows:

Client ID	Lab No.	Return Pressure (mmHg)
3M Abator Upstream Tap	202163-14924	164.2
3M Abator Downstream Tap	202163-14925	186.8

This analysis is performed in accordance with AAC's Quality Manual. For detailed information pertaining to specific EPA, NCASI, ASTM and SCAQMD accreditations (Methods & Analytes), please visit our website at www.aaclab.com.

I certify that this data is technically accurate, complete, and in compliance with the terms and conditions of the contract. No problems were encountered during receiving, preparation, and/or analysis of these samples.

The Technical Director or his/her designee, as verified by the following signature, has authorized release of the data.

If you have any questions or require further explanation of data results, please contact the undersigned.

Sucha Parmar, Ph.D.
Technical Director

This report consists of 4 pages.

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Atmospheric Analysis & Consulting, Inc.

LABORATORY ANALYSIS REPORT

CLIENT	: TRC	SAMPLING DATE	: 11/30/2020
PROJECT NO.	: 202163	RECEIVING DATE	: 12/01/2020
MATRIX	: Air	ANALYSIS DATE	: 12/02/2020
UNITS	: ppmV	REPORT DATE	: 12/03/2020

Ethylene Oxide Analysis by EPA 18 Modified

Client ID	3M Abator Upstream Tap		SRL (RL x DF's)	3M Abator Downstream Tap		SRL (RL x DF's)	Reporting Limit (RL)
AAC ID	202163-14924			202163-14925			
Canister Dil. Fac.	5.6			4.9			
Analyte	Result	Analysis Dil. Fac.		Result	Analysis Dil. Fac.		
Ethylene Oxide	2661	10	28	<SRL	1	2.5	0.5

Sample Reporting Limit (SRL) is equal to Reporting Limit (RL) x Canister Dilution Factor x Analysis Dilution Factor (if applicable)

Sucha Parmar, Ph.D.
Technical Director

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Quality Control/Quality Assurance Report

Date Analyzed	: 12/02/2020	Instrument ID	: FID #3
Analyst	: CH/DL	Calb Date	: 07/01/20
Units	: ppmv	Reporting Limit	: 0.1 ppmV

I - Opening Continuing Calibration Verification - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
CCV	Spike Conc	37.50
	Result	37.23
	% Rec *	99.3

II - Method Blank - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
MB	Concentration	ND

III - Laboratory Control Spike & Duplicate - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
Lab Control Standards	Sample Conc	0.00
	Spike Conc	37.50
	LCS Result	38.62
	LCSD Result	38.28
	LCS % Rec *	103.0
	LCSD % Rec *	102.1
	% RPD **	0.9

IV - Sample & Sample Duplicate - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
202163-14925	Sample	0.00
	Sample Dup	0.00
	Mean	0.00
	% RPD **	0.0

V - Matrix Spike & Duplicate- EPA 18 Modified

AAC ID	Analyte	Ethylene Oxide
202163-14925	Sample Conc	0.00
	Spike Conc	37.50
	MS Result	38.75
	MSD Result	39.30
	MS % Rec **	103.3
	MSD % Rec **	104.8
	% RPD ***	1.41

VI - Closing Continuing Calibration Verification - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
CCV	Spike Conc	37.50
	Result	38.63
	% Rec *	103.0

** Must be 85-115%*

*** Must be < 25%*

ND = Not Detected

<RL = less than Reporting Limit

Sucha Parmar, Ph.D.
Technical Director

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TRC
Results you can rely on

202163

Chain of Custody Record

Project Name: Boston Scientific 3M Abator EtO	TRC Contact: David Wainio	T: 651-686-0700
	Email: dwainio@trccompanies.com	
Site Name: Arden Hills Facility	Sampling System Prepared by: D. Wainio	
Project No.: 397311	Samples Recovered by: D. Wainio	

Sub Lab ID	Sample ID Number	Sample Description* (Unit-Location-Method-Run-Container Number)	Date Sampled	Run Time (Optional)	**No. of Containers	Analyses Required: Ethylene Oxide (EtO)					Comments:
14924	3M Upstream Tap	3M Abator Upstream Tap	11/30/2020		1	x					Summa 000093
14925	3M Downstream Tap	3M Abator Downstream Tap	11/30/2020		1	x					Summa 000380

General Instructions: This form documents all changes in custody. The name and dated signature for each person associated with the release or receipt of the listed samples must be recorded.

TAT: Rush	Need By Date: 12/4/2020	Project Remarks:	Relinquished by: (Sign & Print)	Date/Time	1	Date/Time
Shipped by: FedEx	Shipped On: 11/30/2020		[signature]	11-30-2020	[signature]	12/1/20
Ship To Attn: John Yokoyama			DAVID WAINIO			1418
Lab: Atmospheric Analysis & Consulting, Inc.						
Address: 1534 Eastman Avenue, Suite A Ventura, California 93003						
Phone: 805-650-1642						

Special Instructions: Samples are to be analyzed for Ethylene Oxide (EtO) per EPA Method 18 as specified in price quote 5863.

Please Rush sample analysis 24-48 hour turnaround.

SUBCONTRACTOR LABORATORY MUST CONTACT THE CITED TRC CONTACT TO ENSURE A PO IS IN PLACE.

TRC Environmental Corporation
1301 Corporate Center Drive, Suite 177
Eagan, Minnesota 55121 USA
T: (651) 686-0700 F:(651) 686-4434

Ft 2 cans